Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0366595	11/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Trinity Health Iha Medical Group Pediatrics	4350 Jackson Road Suite 100, Ann Arbor, MI	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory director failed to attest to the routine integration of the hematology, bacteriology, and mycology American Proficiency Institute (API) proficiency testing samples into the patient workload for four (3rd in 2016, 2nd and 3rd 2017, and 2nd in 2018) of seven events reviewed. Findings include: 1. On November 27, 2018 at 10:15 AM, record review of the API proficiency testing documents revealed the laboratory director did not sign the attestation statement sheets for the hematology, bacteriology, and mycology testing as follows: a. 3rd event 2016 - hematology and bacteriology throat and urine cultures b. 2nd and 3rd events 2017 - hematology and bacteriology throat and urine cultures, and the mycology testing c. 2nd event 2018 - hematology 2. During the interview on November 27, 2018 at 10:47 AM, the office supervisor confirmed the attestation statement sheet were not signed by the laboratory director.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically

	transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to establish a system to ensure the manually entered patient final test results were entered into the patient's electronic medical record (EMR) for one (#3) of 25 patient charts audited. Findings include: 1. On November 27, 2018 at 12:53 PM, record review of patient charts audited revealed a final hematology hemoglobin (hgb) result was not entered in the EMR system, when queried, the office supervisor was not able to produce the final result in the patient's EMR chart. 2. During the interview on November 27, 2018 at 12: 53 PM, the office supervisor confirmed the final hgb results was not in the patient's EMR chart. ***Repeat Deficiency from May 31, 2017 survey***
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory director failed to ensure the final graded American Proficiency Institute (API) hematology, bacteriology, and mycology proficiency testing reports were reviewed by the appropriate staff for three (2nd and 3rd events in 2017 and 2nd event in 2018) of seven events reviewed. Findings include: 1. On November 27, 2018 at approximately 10:20 AM, record review of the API proficiency testing reports revealed there was no documentation to show the appropriate staff reviewed the final graded proficiency testing reports as follows: a. 2nd and 3rd events 2017 - no laboratory director or testing personnel review b. 2nd event 2018 - no laboratory director or testing personnel review 2. During the interview on November 27, 2018 at 10:47 AM, the office supervisor confirmed the appropriate staff did not review the final graded proficiency testing events.